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PTO/SB/33 (07-05)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) 022956-0233	
	Application Number 10/623,212-Conf. #2862	Filed July 18, 2003
	First Named Inventor Rickey D. Hart	
	Art Unit 3738	Examiner P. B. Prebilic

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [ ] attorney or agent of record. Registration number _____
- [x] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. 44,238


Signature

Lisa Adams
Typed or printed name

(617) 439-2550
Telephone number

July 21, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

1546724.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rickey D. Hart	
Application No.:	10/623,212	Group Art Unit: 3738
Filed:	July 18, 2003	Examiner: Paul B. Prebilic
Entitled:	METHODS FOR ANCHORING AUTOLOGOUS OR ARTIFICIAL TENDON GRAFTS IN BONE	
Docket No.:	22956-233 (MIT-230DIV)	

Certificate of Transmission (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being electronically filed via **EFS-Web** to: **MS Amendment,** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date set forth below.

July 21, 2006 — Date of Signature and Mail Deposit

By: — Lisa Adams, Reg. No: 44,238
Attorney for Applicant(s)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS FOR PRE-APPEAL BRIEF REVIEW

Dear Sir:

These comments are being filed concurrently with a Notice of Appeal, and a Pre-Appeal Brief Request for Review.

A clean version of the ***Pending Claims*** is attached hereto.

REMARKS

Claims 61-65, 67-69, 71-89, and 95 and pending. Claims 84-89 and 95 are allowed, and remaining claims 61-65, 67-69, 71, and 75-83 stand rejected.

Claims 61, 62, and 67

Claims 61, 62, and 67 stand rejected pursuant to 35 U.S.C. §103(a) as being obvious over Kenna in view of U.S. Patent 5,084,050 of Draenert or U.S. Patent No. 5,725,529 of Nicholson et al. ("Nicholson"). The Examiner argues that Kenna discloses the claimed method, except for obtaining a pressure fit or compression fit within the bone opening. Applicants further note that Kenna fails to teach a sleeve that *deformably expands*, and a stem having a diameter *greater* than a diameter of an axial channel of the sleeve. The Examiner relies on Draenert or Nicholson to teach devices that obtain a pressure or compression fit within a bone opening, arguing that it would have been obvious to modify the device of Kenna in view of Draenert or Nicholson to arrive at the claimed invention "in order to provide a more secure attachment to the same."

The pending rejection is deficient because the Examiner has not established a prima facie case of obviousness in support of the pending rejection. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference, or references when combined, must teach or suggest all of the claim limitations. The Examiner has failed to meet the first and second criteria.

With respect to the first criteria, the Examiner has failed to provide a suggestion or motivation to modify Kenna in view of Nicholson or Draenert. The Examiner argues that one would be motivated to modify Kenna in view of Nicholson or Draenert "in order to provide a more secure attachment" between the first and second portions of Kenna. Kenna, however, already provides a secure attachment between the first and second portions, and in fact the irreversible mechanical connection taught by Kenna is likely more secure than a compression fit, as taught by Nicholson and Draenert. Applicants refer the review panel to the arguments previously presented and set forth in the first full paragraph starting on page 9 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on June 19, 2006.

With respect to the second criteria, the Examiner has failed to show a reasonable expectation of

success when modifying Kenna in view of Nicholson or Draenert. As explained in the last paragraph starting on page 8 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on June 19, 2006, no person having ordinary skill in the art would modify Kenna to increase the diameter of the second portion of the device, to make the first portion of the device deformably expandable, and to cause the two portions to obtain a pressure fit within bone when the portions are mated because such a modification would require a substantial reconstruction and redesign of the elements of Kenna as well as a change in the basic principal under which the Kenna construction was designed to operate.

First, Kenna cannot be modified to increase the diameter of the inner component. In the Advisory Action the Examiner argues that one could slightly modify the diameter of the inner component of Kenna to provide a compression fit, while still allowing the inner component to fit within the outer component. This is incorrect. If the diameter of the inner component of Kenna is only slightly increased so as to allow it to fit within the outer component, then the inner component would not be capable of deformably expanding the outer component. The only way Kenna can be modified to allow the inner component to deformably expand the outer component is to modify the inner component to have an outer diameter that is *larger* than the inner diameter of the outer component. The pins located on the inner component, however, would prevent such a modification as the pins protrude outward from the inner component and thus will not fit within the outer component. The pins also cannot simply be removed to allow the two components to mate using a compression fit, because such a modification would require that the snap-lock mechanisms of Kenna, which is the principal operation of the device, be completely disregarded. As set forth in the Manual of Patent Examining Procedure (MPEP), a proposed modification cannot change the principle operation of a reference. MPEP 2143.01(VI); see also *In re Ratti*, 270 F.2d 810 (CCPA 1959).

Second, the outer component of Kenna cannot be modified to be deformable. As previously explained, the outer component of Kenna is threaded to allow the component to be threaded into and to engage a bone hole. Modifying the outer component to be deformable, as suggested by the Examiner, would prevent the threads from functioning. Rather, the outer component would merely deform or collapse inward as it is inserted into bone.

Accordingly, the Examiner has failed to establish a prima facie case of obviousness, and therefore claim 61 distinguishes over Kenna, Nicholson, and Draenert, taken alone or combined. Claims 62 and 67 are allowable at least because they depend from claim 61.

Claims 69, 75-80, and 82

Claims 69, 75-80, and 82 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Kenna in view of Draenert or Nicholson, as applied to claims 61, 62, and 67, and further in view of U.S. Patent No. 5,725,529 of Li.

Claim 69 depends from claim 61, and therefore distinguishes over Kenna, Draenert, and Nicholson for the same reasons discussed above with respect to claim 61. Li is merely relied on by the Examiner to teach looping grafts through apertures, as claimed, thus Li does not remedy the deficiencies of these references. Claim 69 therefore represents allowable subject matter.

Independent claim 75 recites a method for replacing a torn ligament including the steps of obtaining a tendon graft, drilling a hole into bone, looping the tendon graft through an aperture in an insertion element, inserting a stabilizing element into the bone hole, and inserting the insertion element into the stabilizing element. Claim 75 further requires that the insertion element be held in the stabilizing element by compression fit. For the same reasons previously discussed with respect to claim 61, it would not have been obvious to a person having ordinary skill in the art to modify Kenna to use a compression fit, as taught by Nicholson and Draenert. As noted above, Li is merely relied on by the Examiner to teach looping grafts through apertures, as claimed, thus Li does not remedy the deficiencies of these references. Claim 75 therefore distinguishes over Kenna, Nicholson, Draenert, and Li, taken alone or combined, and represents allowable subject matter. Claims 76-80 and 82 are allowable at least because they depend from claim 75.

Claim 81

Claim 81 is rejected pursuant to 35 U.S.C. §103(a) as being obvious over Kenna, Draenert, Nicholson, and Li as applied to claims 69, 75-80, and 82, and further in view of Kenna or U.S. Patent No. 3,953,896 of Treace. Claim 81 depends from claim 75, and therefore distinguishes over Kenna, Draenert, and Nicholson for the same reasons discussed above with respect to claim 75. Kenna and Treace are merely relied on by the Examiner to teach the use of flanges, as claimed, thus Kenna and Treace do not remedy the deficiencies of these references. Claim 81 therefore represents allowable subject matter.

Conclusion

In view of the above remarks, Applicant submits that all claims are in condition for allowance,

and allowance thereof is respectfully requested.

Respectfully submitted,

Date: July 21, 2006

Lisa Adams, Reg. No. 44,238
Attorney for Applicant

NUTTER, McCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02110
Tel: (617) 439-2550
Fax: (617) 310-9550

PENDING CLAIMS

1-60. (Canceled).

61. (Previously Presented) A method for anchoring soft tissue within bone comprising:

drilling an opening into bone;

inserting into said bone opening a stabilizing element comprising an elongated sleeve with an axial channel extending therethrough;

threading soft tissue through an aperture in an insertion element comprising an aperture-containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve; and

inserting the distal end of said insertion element into a proximal end of said stabilizing element to cause the stabilizing element to deformably expand and obtain a pressure fit within the bone opening.

62. (Original) The method according to claim 61, wherein said soft tissue is a tendon graft.

63. (Original) The method according to claim 61, wherein the method of drilling said opening comprises creating a stepped opening.

64. (Original) The method according to claim 63, wherein the stepped opening has at least two different diameters, one less than the diameter of the stabilizing element, and one greater than the diameter of the stem head.

65. (Original) The method according to claim 64, wherein said elongated sleeve of said stabilizing element is screwed into said bone opening at the diameter where said stepped bone opening is slightly smaller than that of said elongated sleeve.

66. (Original) The method according to claim 65, wherein said axial channel in the stabilizing device is non-cylindrical, and wherein said stabilizing element is screwed into said stepped bone opening by use of an emplacement device fitted into said non-cylindrical axial channel.

67. (Original) The method according to claim 61, wherein said insertion element retaining said soft tissue is inserted forcibly into said stabilizing element screwed into said stepped bone hole.

68. (Previously Presented) The method according to claim 61, wherein said stabilizing element includes a flange at its distal end, whereby upon insertion of the stabilizing element in the bone opening, the flange is disposed at least partially outside the bone opening in a configuration whereby it will oppose further movement of the stabilizing element into the bone opening.

69. (Previously Presented) The method of claim 61, further comprising:

drilling a second opening into bone;

inserting into said second bone opening a second stabilizing element comprising an elongated sleeve with an axial channel extending therethrough;

threading the soft tissue through an aperture in a second insertion element comprising an aperture-containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve; and

inserting the distal end of said second insertion element into a proximal end of said second stabilizing element.

70. (Canceled).

71. (Previously Presented) The method of claim 61, wherein said stabilizing element includes a flange at its distal end, whereby upon insertion of the stabilizing element into a bone opening, the flange is disposed at least partially outside the bone opening in a configuration whereby it will oppose further movement of the stabilizing element into the bone opening.

72. (Previously Presented) A method for anchoring soft tissue within bone comprising:

drilling an opening into bone;

inserting into said bone a stabilizing element comprising an elongated sleeve with an axial channel extending therethrough;

threading soft tissue through an aperture in an insertion element comprising an aperture containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve; and

pulling the distal end of said insertion element into a proximal end of said stabilizing element.

73. (Previously Presented) The method of claim 72, further comprising:

drilling a second opening into bone;

inserting into said second bone opening a second stabilizing element comprising an elongated sleeve with an axial channel extending therethrough;

threading the soft tissue through an aperture in a second insertion element comprising an aperture-containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve; and

inserting the distal end of said second insertion element into a proximal end of said second stabilizing element.

74. (Original) The method of claim 73, wherein at least one of the stabilizing element and the second stabilizing element comprises a flange at its distal end, whereby upon insertion of the stabilizing element into a bone opening, the flange is disposed at least partially outside the bone opening in a configuration whereby it will oppose further movement of the stabilizing element into the bone opening.

75. (Previously Presented) A method for replacing a torn ligament comprising:

obtaining a tendon graft;

drilling a hole into bone;

looping said tendon graft through an aperture in an insertion element;

inserting a stabilizing element comprising a sleeve with a cavity therein into said hole; and

inserting an insertion element comprising a stem with an aperture-containing stem head at the proximal end of said stem into said stabilizing element, the insertion element being held in the stabilizing element by a compression fit.

76. (Original) The method of claim 75, wherein said ligament is an anterior cruciate ligament and said bone aperture is in either a femur or tibia.

77. (Previously Presented) The method of claim 75, further comprising:

drilling a second opening into bone;

inserting into said second bone opening a second stabilizing element comprising an elongated sleeve with an axial channel extending therethrough;

looping the tendon graft through an aperture in a second insertion element comprising an

aperture-containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve; and

inserting the distal end of said second insertion element into a proximal end of said second stabilizing element.

78. (Original) The method of claim 77, wherein said ligament is an anterior cruciate ligament, said bone opening is in a femur, and said second bone opening is in a tibia.

79. (Original) The method of claim 77, wherein at least one of said stabilizing element and said second stabilizing element is affixed into bone by an interference fit.

80. (Original) The method of claim 77, wherein at least one of said stabilizing element and said second stabilizing element is affixed into bone by means of screw threads.

81. (Original) The method of claim 77, wherein at least one of said stabilizing element and said second stabilizing element comprises a flange at its distal end, whereby upon insertion of the stabilizing element into a bone opening, the flange is disposed at least partially outside the bone opening in a configuration whereby it will oppose movement of the stabilizing element into the bone opening.

82. (Original) The method of claim 75, wherein said stabilizing element is affixed into bone by interference fit.

83. (Original) The method of claim 75, wherein said stabilizing element comprises a flange at its distal end, whereby upon insertion of the stabilizing element into a bone opening, the flange is disposed at least partially outside the bone opening in a configuration whereby it will oppose further movement of the stabilizing element into the bone opening.

84. (Original) A method for replacing a torn ligament comprising:

obtaining a tendon graft;

drilling a hole into bone;

looping said tendon graft through an aperture in an insertion element;

inserting a stabilizing element comprising a sleeve with a cavity therein into

said hole; and

pulling an insertion element comprising a stem with an aperture containing stem head at the proximal end of said stem and any of an aperture, slot and barb at the distal end of said stem.

85. (Original) The method of claim 84, further comprising:

drilling a second opening into bone;

inserting into said second bone opening a second stabilizing element comprising an elongated sleeve with an axial channel extending therethrough;

looping the tendon graft through an aperture in a second insertion element comprising an aperture-containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve, and any of an aperture, slot, and barb at the distal end of said stem; and

pulling the second insertion element into the stabilizing element.

86. (Original) The method of claim 85, wherein said ligament is an anterior cruciate ligament, said bone opening is in a femur, and said second bone opening is in a tibia.

87. (Original) The method of claim 85, wherein at least one of said stabilizing element and said second stabilizing element is affixed into bone by an interference fit.

88. (Original) The method of claim 85, wherein at least one of said stabilizing element and said second stabilizing element is affixed into bone by means of screw threads.

89. (Original) The method of claim 85, wherein at least one of said stabilizing element and said second stabilizing element comprises a flange at its distal end, whereby upon insertion of the stabilizing element into a bone opening, the flange is disposed at least partially outside the bone opening in a configuration whereby it will oppose movement of the stabilizing element into the bone opening.

90-94. (Canceled).

95. Previously Presented) A method for anchoring soft tissue within bone comprising:

drilling a stepped opening into bone;

inserting into said stepped bone opening a stabilizing element comprising an elongated sleeve with a non-cylindrical axial channel extending therethrough, wherein said stabilizing element is screwed into said stepped bone opening by use of an emplacement device fitted into said non-cylindrical axial channel;

threading soft tissue through an aperture in an insertion element comprising an aperture-containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve; and

inserting the distal end of said insertion element into a proximal end of said stabilizing element.

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